1617

PTO/SB/21 (09-04)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission: 33

Application Number	09/614,790
Filing Date	July 12, 2000
First Named Inventor	Sharon F. Kleyne
Art Unit	1617
Examiner Name	Wang, Shengjun
Attorney Docket Number	HME/7982.001

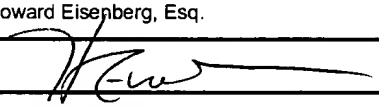
ENCLOSURES *(Check all that apply)*

- [✓] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [✓] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
  - [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
  - [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [✓] Other Enclosure(s) (please Identify below):
  1. British J. Ophthalmology, 74:477-480 (1990) (4 pages)
  2. Pubmed Search (12 pages)
  3. Pubmed Abstracts (9 pages)

Remarks

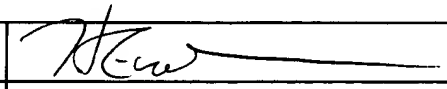
Declaration (Second) of Dr. William D. Mathers (6 pages) plus attachments listed above under "Other Enclosures"

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Howard Eisenberg, Esq.		
Signature			
Printed name	Howard Eisenberg		
Date	May 10, 2005	Reg. No.	36,789

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name	Howard Eisenberg	Date	May 10, 2005

PTO/SB/17 (12-04v2)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2005

☑ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 0

Complete if Known	
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First Named Inventor	Sharon F. Kleyne
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Art Unit	1617
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METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☑ None ☐ Other (please identify): _____

☐ Deposit Account Deposit Account Number: 50-1773 Deposit Account Name: Howard Eisenberg

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee

☑ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☑ Credit any overpayments

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES Fee ($)	FILING FEES Small Entity Fee ($)	SEARCH FEES Fee ($)	SEARCH FEES Small Entity Fee ($)	EXAMINATION FEES Fee ($)	EXAMINATION FEES Small Entity Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims	Extra Claims	Fee ($)	Fee Paid ($)
8 - 20 or 43 =	0	x 25	= 0

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims	Extra Claims	Fee ($)	Fee Paid ($)
2 - 3 or 5 =	0	x 100	= 0

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims Fee ($)	Multiple Dependent Claims Fee Paid ($)

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee ($)	Fee Paid ($)
_____ - 100 =	_____ / 50 =	_____ (round up to a whole number) x	_____	= _____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other (e.g., late filing surcharge): _____	

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 36,789	Telephone (215) 453-9237
Name (Print/Type)	Howard Eisenberg		Date May 10, 2005

Atty Doc. No. HME/7982.001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT APPLICATION EXAMINING OPERATIONS

In re the Application of Sharon F. Kleyne	: :	Group Art Unit: 1617
Serial No. 09/614,790	:	Examiner: Shengjun Wang
Filed: July 12, 2000	:	Tel. No. (571) 272-0632
For a Patent for METHOD AND KIT FOR MOISTURIZING THE SURFACE OF THE EYE	:	

SECOND DECLARATION OF DR. WILLIAM D. MATHERS
37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir,

1. I, William D. Mathers, MD, am a Professor of Ophthalmology at Oregon Health and Science University – Casey Eye Institute in Portland Oregon. I filed a previous Declaration in relation to this application in January 2004. A copy of my curriculum vitae was attached to my previous Declaration. My previous Declaration also briefly described my relationship with Rogue Valley Natural Springs, Inc., the assignee of this application. I am familiar with the prosecution of this application in the U.S. Patent Office.

2. I am submitting this Declaration to provide additional evidence to that which has already been submitted to establish that this invention is not obvious. In particular, I am submitting this Declaration to demonstrate that this invention provides a solution to a long-

standing problem pertaining to the treatment of patients suffering from symptoms of dry eyes, the problem of a lack of patient compliance in the use of topical dry eye therapies.

3. It has long been recognized in the field of ophthalmology that many, if not most, patients requiring the administration of eye drops fail to comply in part or at all with the recommendations of their treating physician. Attached to this Declaration as Exhibit I is an article, Winfield, et al, "A Study of the Causes of Non-Compliance by Patients Prescribed Eyedrops", British Journal of Ophthalmology, 74:477-480 (1990). This article discusses the problem of the lack of patient compliance in the use of eyedrops and addresses several causes for this lack of compliance.

4. The data disclosed in the Winfield et al article shown in Table 1 on page 478 show that only 64% of patients use eye drops as directed and, even more striking, that only 62% of patients administer their own drops. As stated in the first full paragraph on page 478, second column: "Over a third of patients did not administer their own drops regularly, with 21% always using assistance. . . . In total, 57% of patients admitted having some difficulty administering their drops."

5. Table 2 on page 478 presents the main problems that patients have with administering eye drops. As stated on page 478, second column, first full paragraph: "Discussion with patients indicated that lack of confidence was a major factor, particularly fear of prodding the eye. As a result the bottle was often held too far from the eye, making the aim more difficult and encouraging the blink reflex. Older patients experienced physical problems in

raising the arm, tilting the head, and in holding and squeezing the bottle." Table 3 on the bottom of page 478 shows that many patients do not aim eyedrops well.

6. On page 479, first column, last paragraph, Winfield et al summarize their conclusions: "From this work it appears that we have identified two interrelated problems with the self administration of eyedrops: firstly, the lack of physical acuity, and secondly the inability to aim adequately." On page 479, second column, last paragraph, Winfield et al conclude that: "Apart from the evidence we have produced, demographic trends indicate that the number of patients experiencing difficulty will increase rather than decrease. Difficulty in administering drops increases with age. Projections indicate that the population of 85 years old and above will increase by a third over the next 10 years."

7. A recent search on the PubMed database shows that the problem of lack of patient compliance in the use of eyedrops for the treatment of symptoms relating to dry eyes is one that has been recognized by researchers in the field of ophthalmology for quite some time. Attached to this Declaration as Exhibit 2 is a PubMed search that looked for articles dealing with subjects related to the Winfield article. The search produced a listing of 114 articles, many of which deal with the problem of lack of compliance, with the difficulty in administering eyedrops, or with means for facilitating eyedrop administration. From a reading of the titles in the search, it appears to me that articles 1-14, 16, 18-20, 23-26, 28-29, 31-33, 35, 44, 46-48, 60-62, 78-80, 83, 86, 91, 93, 100, 101, 106, 108, 109, 113 deal with problems relating to the administration of eyedrops, with the vast majority of these articles dealing with the problem of lack of patient compliance.

8. Attached to this Declaration as Exhibit 3 are abstracts of articles numbered 2, 5, 7, 20, 23, 33, 46, and 62 of the PubMed search. These articles deal with various aspects of the problem of lack of patient compliance and make clear that the issue of non-compliance with eyedrops is a long standing one due to difficulties that patients have in self-administration.

9. In my Declaration of January 2004, I submitted data from a survey of 39 patients who either had dry eye (33) or had other reasons for needing an eye care product for moisturizing the eye (6). Of these 39 patients, 35 (89%) had previously used other eye care products and of these 72% (25) had experienced favorable results with those products. The patients were given Nature's Tears to use freely for 2 weeks, as needed. Telephone interviews were conducted after the two week period. Nature's Tears is a commercial embodiment of the invention with which a user moisturizes his/her eyes by spraying a mist of water towards the face. The use of Nature's Tears does not require an individual to aim precisely to the eye and does not require an individual to bend the neck so as to look upward, as is required when moisturizing the eye with eyedrops.

10. Of the 39 patients, 83% (32) found Nature's Tears to be more convenient than the other products that they had used (eyedrops). Only 8% (2) found Nature's Tears to be less convenient, and 8% (2) found the convenience of Nature's Tears to be about the same. One patient in the survey stated that she preferred Nature's Tears over eyedrops because she has arthritis. Due to the debilitating condition in her hands, she found Nature's Tears to be much easier to use.

11. In January 2004, Dr. Darwin Liao, an ophthalmologist in Seattle, Washington, submitted a Declaration. In the Declaration of Dr. Liao, he testified that he cares for many patients who suffer from dry eyes and that his experience with conventional eyedrop therapies had not been entirely successful. He testified that many of his patients have complained of difficulty in the administration of eyedrops and that this problem of difficulty in administration of eyedrop therapy occurs very frequently and is a serious issue in elderly patients and in patients with motor difficulties. Dr. Liao summarized his experience with conventional eyedrops by stating that he had experienced problems in patient compliance because many of his patients applied the eye drops less frequently than recommended or discontinued use of them completely.

12. Dr. Liao then testified that the results that he has obtained with Nature's Tears have been outstanding. He stated that he no longer receive complaints about discomfort upon or after application or about difficulty in applying eye moisturizing therapy. Many of his patients have even commented about how good their eyes feel when they use Nature's Tears. Significantly, Dr. Liao testified that his patients continue to use Nature's Tears because it is effective in reducing symptoms of dry eye and the mist is very easy and comfortable to apply to the eye. His elderly patients, many of whom suffer from secondary eye conditions due to eyelid laxity and other such disorders, and his patients with motor difficulties find the Nature's Tears mist very easy to apply. Therefore, Dr. Liao concluded, he no longer has problems with patient compliance with dry eye topical therapy in his ophthalmology practice now that he dispenses Nature's Tears.

13. The references referred to above establish that the problem of lack of patient compliance with present methods of moisturizing the eye has been a longstanding problem and that the solution to this problem has proven to be evasive. The data from my study of 39 patients described in my previous Declaration of January 2004 and the testimony in the Declaration of Dr. Darwin Liao also of January 2004 establish that the use of Nature's Tears eye mist increases patient compliance regarding the use of eye moisturizes and that the present invention provides a solution to the longstanding problem of lack of patient compliance with eye moisturizing products.

Further, Deponent sayeth naught.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

5/5/2005
Date

William D. Mathers, MD

Attachments: (1) Exhibit 1: Winfield, et al, British Journal of Ophthalmology, 74:477-480 (1990)
(2) Exhibit 2: PubMed search listing 114 articles
(3) Exhibit 3: Selected abstracts (8) from articles listed in PubMed search